Mitchell E. Daniels, Jr.
Governor

Judith A. Monroe, M.D.
State Health Commissioner

Indiana State Department of Health

An Equal Opportunity Employer

IN RE THE MATTER OF:

Vicki S. Farmwald
Hacienda Mexican Restaurants
1501 N. Ironwood Drive
South Bend, IN 46635

Re: Variance Request Dated May 6, 2009 and Section 195, Reduced Oxygen Packaging (ROP); criteria

Order to Deny a Variance

You are hereby notified that based on the recommendation of the Food Protection Program, Indiana State Department of Health (ISDH), and as authorized by Indiana Code (IC) 16-19-3-4.3 and IC 16-42-5-5.2, the State Health Commissioner hereby orders that a variance be denied to Vicki S. Farmwald, Hacienda Mexican Restaurants, 1501 N. Ironwood Drive, South Bend, IN 46635.

This variance denial is based on the variance application submitted on May 6, 2009. As part of the review of the variance application, an ISDH representative conducted an on-site evaluation to determine if and how the procedures put into place were being administered and monitored.

Order

This **VARIANCE DENIAL** is based on the following criteria:

1. The application was incomplete in that supporting documentation to demonstrate how your proposed plan would be implemented was not submitted. Examples of supporting documentation are, but not limited to, the following:
    a. A complete list of foods to which reduced oxygen packaging (ROP) is applied;
        i. At the time of the on-site visit, the following food items not included in the Variance document were being ROP'd according to a list provided to the ISDH representative by Ms. Jen Godfey, General Manager:
            1. Cheese soup
            2. Chicken fajita chili
            3. Enchilada sauce
            4. Garlic mushrooms
            5. Pablano cream sauce
            6. Diced red skin potatoes (raw)
            7. Fresh-cut Roma tomatoes

8. Mexican rice

b. The hazard analysis critical control point (HACCP) plan for each food to which ROP is applied;

2. The application references the use of the 2005 Food and Drug Administration (FDA) Model Food Code (MFC) Section 3-502.12 *Reduced Oxygen Packaging, Criteria.* Although the document has not been adopted in Indiana and is not referenced in the ISDH Retail Food Sanitation Requirements Rule 410 IAC 7-24, the use of the document was considered. However, the entire section 3-502.12(D) was not incorporated into the operation, as observed during the on-site visit and/or the standard operating procedure (SOP) submitted with the application and therefore is not valid. In response, the following bullets detail the various omissions.
   a. The hazard analysis critical control point (HACCP) plan, in compliance with section 8-201.14 of FDAMFC, was not provided for each food to which ROP is applied according to the original list provided by the General Manager during the on-site visit;
   b. The HACCP plans developed and provided by the establishment in the variance document do not appear to be complete;
   c. Leftover food items are donated to local food banks/charities according to the General Manager during the on-site visit; this is not consistent with subsection 2(a) under section 3-502.12(D) which states: "The food is prepared and consumed on the premises."
   d. At the time of the on-site visit, poor practices not consistent with subsection 2(b) under section 3-502.12(D) which states: "The food is protected from contamination after cooking" were observed during the establishment review, including:
      i. Incomplete separation of ROP process from other daily restaurant activities
      ii. Cooked product placement next to common aisle and not protected from overhead contamination

      In addition, the submittal stated procedures for protecting food after packaging rather than after cooking. This issue was not addressed in the application.
   e. At the time of the on-site visit, it was observed that the employee did not at any time measure the a temperature of the bulk product during packaging to verify the product was maintained at 135 F or above. This is not consistent with subsection 2(d) under section 3-502.12(D) which states: "The food is placed in a package or bag with an oxygen barrier before cooking, or placed in a package or bag immediately after cooking and before reaching a temperature below 57 C (135 F). This item was not addressed in the application.

3. The establishment's HACCP Plan for each product lacked several crucial items outlined in section 8-201.14 FDAMFC and 410 IAC 7-24 – 195, Retail Food Establishment Sanitation Requirements, including:
   a. A hazard analysis describing the biological, chemical and physical hazards likely to occur. This is not consistent with 8-201.14(A), which states that a

food establishment's HACCP Plan shall have specifications that indicate "a categorization of the types of potentially hazardous foods that are specified in the menu...or of other foods that are specified by the regulatory authority."

b. An incomplete flow diagram observed during the establishment review. This is not consistent with 8-201.14(B), which states that a food establishment's HACCP Plan shall have specifications that indicated "a flow diagram by specific food or category type identifying Critical Control Points" (CCP). Subsection 2 under 8-201.14(B) stipulates that the flow diagram must provide information regarding "formulations or recipes that delineate methods and procedural control measures that address the food safety concerns involved." Such food safety concerns were not delineated anywhere in any of the recipes provided by the establishment in its HACCP Plan for each food product. In addition, the recipes provided did not reflect all critical control points (CCP's) listed in standard operating procedures (SOP's) while some were not addressed at all. This should be done for consistency purposes.
c. Training that does not specifically address the food safety concerns associated with the items packaged and the ROP process itself. This is not consistent with 8-201.14(C) which states a food establishment's HACCP Plan shall indicate a "food employee and supervisory training plan that addresses the food safety issues of concern." In addition, the establishment's HACCP Plan did not define or explain what constitutes a "ROP certified technician."
d. A complete statement of standard operating procedures (SOP). This is not consistent with 8-201.14(D).
    i. The establishment's HACCP Plan addressed date marking in the recipe rather than in the SOP. Date marking should be included in the SOP because it is a CCP.
    ii. Subsection 1 under 8-201.14(D) stipulates that the HACCP Plan under consideration include a statement of SOP's that clearly identifies each critical control point.
        1. The establishment's SOP's state that the product will be cooled and held to/at 38 F. The review established that this temperature could not be attained in the walk-in cooler.
        2. The establishment's SOP's do not identify maintaining the product over 135 F during packaging as a CCP.
        3. The establishment's SOP's do not address the entire actual flow of the food as packaging (holding product at 135 F or above) and leftovers are not included in the flow diagram.
    iii. Subsection 3 under 8-201.14(D) stipulates that the HACCP Plan under consideration include a statement of SOP's that clearly identifies the method and frequency for monitoring and controlling each CCP by the food employee designated by the person-in-charge. The following elements of the establishment's HACCP Plan were determined to be not consistent with this subsection because they were either unclear (1 and 2), incorrect (3), insufficient (4) or unacceptable (5):
        1. Whether a HACCP Chart (as submitted) would be completed for each product that is ROP'd in a day.

2. Whether temperatures are internal product temperatures or ambient air temperatures.
3. Cold holding appears to be recorded as an ambient air temperature.
4. The HACCP Chart does not incorporate all of the cooling requirements. Cooling is recorded after 2 hours and 6 hours, not after 24 hours, which is required for 38 F maximum holding temperature specified in 3-502.12.
5. There is no electronic system for continuous monitoring of time and temperature as required. The integral digital thermometer currently utilized by the establishment is not considered continuous. Subsection 2(f) under Section 3-502.12 stipulates that ROP'd food products must be "held in refrigeration that is equipped with an electronic system that continuously monitors time and temperature and is visually examined for proper operation twice daily."

iv. Subsection 4 under 8-201.14(D) stipulates that the HACCP Plan under consideration include SOP's that clearly identify the method and frequency for the person in charge to routinely verify that the food employee is following SOP's and monitoring CCP's. The verification paperwork submitted by the establishment is too generic and is not specific to food products being ROP'd.
   1. It is unclear what is meant by "conduct a line check using HACCP Chart and Food Quality Checklist" as phrased in the establishment's submitted Manager Time Line.
   2. The verification paperwork does not specify if the manager is conducting line checks and checking each ROP'd product.
   3. The Manager Time Line does not stipulate if a HACCP chart will be completed for each ROP'd product daily.
   4. The Food Quality Checklist submitted by the establishment does not appear to address ROP issues.

v. Subsection 5 under 8-201.14(D) stipulates that the HAACP Plan under consideration include SOP's that clearly identify action to be taken by the person in charge if the critical limits for each critical control point are not met. The establishment review revealed the packages were being held for 5 days even though the manager stated 4 days as the day of food preparation and cooking was not included, as it should have been.

4. The establishment's application for variance stated that its implementation of the variance would be practical because it "has all the necessary equipment and facilities to comply with Section 3-502.12(D) and its personnel have over 10 years of training and experience packaging and storing ROP food in compliance with Section 3-502.12(D)." However, upon review of the establishment, the following critical items were observed:

a. The applicant does not have all of the necessary equipment, including a walk-in cooler that is capable of maintaining 38 F and an electronic system that continuously monitors time and temperature.
b. The facilities do not currently allow for a complete separation by time or space for the ROP process.
c. Employee training is not focused on the concerns related to the ROP process.
d. Information regarding the oxygen transmission rate of the packaging material used in the ROP process was not provided.
e. The cooling process, observed during the on-site visit, did not meet the cooling process delineated in section 3-502.12(D) (2)5(e). If the product is not cooled as described in section 3-502(D) (2)5(e), then "shelf-life" is not an acceptable barrier.
f. The records required to confirm that cooling and cold holding refrigeration time/temperature parameters are required as part of the HACCP plan, were not maintained and made available to the regulatory authority upon request or held for six (6) months.

5. If not in compliance with section 3-502.12(D) (2)5(e) of FDAMFC, then it would be necessary to comply with section 195 of ISDH 410 IAC 7-24. The following list of items were not included in your submittal:
   a. Documentation which reveals that Clostridium botulinum is or is not a microbiological hazard in the foods that undergo ROP in the establishment.
   b. Documented proof of the two barriers in place to control the growth and toxin formation of Clostridium botulinum.
   c. The hazard analysis critical control point (HACCP) plan, in compliance with section 115(a)(4) of 410 IAC 7-24 and section 195(b)(1-7) was not provided for each food to which ROP is applied;

If you wish to request an administrative review or stay of effectiveness of this decision pursuant to Ind. Code §4021.5-3-7(a), you must petition for such review in writing. The petition must state facts demonstrating that:

a. you are a person to whom the decision is specifically directed;

b. you are aggrieved or adversely affected by the decision; or,

c. you are entitled to review under any law.

Your request for review or stay of effectiveness must be filed in writing with the State Health Commissioner, 2 North Meridian Street, Indianapolis, Indiana 46204, on or before August 10, 2009. If no request for review or stay of effectiveness is filed by August 10, 2009, this decision shall become final.

DATED AT INDIANAPOLIS, INDIANA, THIS 23 DAY OF JULY, 2009.

PURSUANT TO IC 16-19-3-4.3 AND IC 16-42-5-5.2, I HEREBY DENY A VARIANCE OF FOOD PROTECTION RULES AS STATED ABOVE.

JUDITH A. MONROE, M.D.
STATE HEALTH COMMISSIONER

By: 

Loren Robertson
Deputy State Health Commissioner
Indiana State Department of Health

cc: ISDH Food Protection Staff
ISDH Office of Legal Affairs
Local Health Departments in Indiana